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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/692,785	10/27/2003	Egisto Boschetti	9676-314-999	1038
20583	7590	07/12/2007		
JONES DAY 222 EAST 41ST ST NEW YORK, NY 10017			EXAMINER JONES, DAMERON LEVEST	
			ART UNIT	PAPER NUMBER
			1618	
			MAIL DATE	DELIVERY MODE
			07/12/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/692,785	Applicant(s) BOSCHETTI, EGISTO	
	Examiner D. L. Jones	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 April 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4-11,15-21,56-60 and 63-68 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4-11,15-21,56-60 and 63-68 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>4/11/07 & 11/7/06</u> . | 6) <input type="checkbox"/> Other: _____ |

ACKNOWLEDGMENTS

1. The Examiner acknowledges receipt of the amendment filed 4/11/07 wherein the title was amended.

Note: Claims 1, 4-11, 15-21, 56-60, and 63-68 are pending.

COMMENTS/NOTES

2. It is duly noted in the response filed 4/11/07, Applicant makes comments regarding the Examiner re-evaluation of the prior art and the making of rejections against the pending claims. First, it should be noted that having re-evaluated the prior art, the Examiner felt that rejections were necessary since it was believed that the instant invention and the cited prior art contained overlapping subject matter. Furthermore, there is nothing unusual, certainly, about an Examiner changing his/her viewpoint as the prosecution of a case progresses, and, so long as the rules of the Patent Office Practice are duly complied with, an Applicant has no legal complaint because of such change in view (In re Ellis, 31 USPQ 380 and In re Becker, 40 USPQ 624).

RESPONSE TO APPLICANT'S AMENDMENT/ARGUMENTS

3. The Applicant's arguments filed 4/11/07 to the rejection of the claims made by the Examiner under 35 USC 103 have been fully considered and deemed non-persuasive for reasons of record in the office action mailed 10/30/06 and those set forth below.

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I. The rejection of claims 1, 4-6, 11, 15-18, and 56-60 under 35 USC 103(a) as being unpatentable over Bachtis et al (J. Microencapsulation, 1995, vol. 12, No. 1, pp. 23-25) is MAINTAINED for reasons of record in the office action mailed 10/30/06 and those set forth below.

II. The rejection of claims 1, 4, 5, 8-11, 15-17, 19-21, 56-60, and 63-68 under 35 USC 103(a) as being unpatentable over Bachtis et al (J. Microencapsulation, 1995, vol. 12, No. 1, pp. 23-25) in view of Tarara et al (US Patent No. 6,565,885) is MAINTAINED for reasons of record in the office action mailed 10/30/06 and those set forth below.

III. The rejection of claims 1, 4-6, 11, 15-18, 56-60, 63-68 under 35 USC 103(a) as being unpatentable over Bachtis et al (J. Microencapsulation, 1995, vol. 12, No. 1, pp. 23-25) in view of Tarara et al (US Patent No. 6,565,885) is MAINTAINED for reasons of record in the office action mailed 10/30/06 and those set forth below.

IV. The rejection of claims 1, 4-11, 15-21, 56-60, and 63-68 under 35 USC 103(a) as being unpatentable over Boschetti et al (US Patent No. 5,635,215) in view of Tarara et al (US Patent No. 6,565,885) is MAINTAINED for reasons of record in the office action mailed 10/30/06 and those set forth below.

In summary, Applicant makes the following assertions regarding the cited prior art documents. (1) The Examiner is misunderstanding the rationale for using NaOH in Bachtisi. The NaOH buffer solution (pH 8-9) is used to remove any unreacted chemicals, not to neutralize the aldehydes on the microspheres). (2) Applicant notes

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that in their Examples Tris-HCl is used as a buffer. (3) Applicant asserts that impermissible hindsight has been used in selecting the Tarara document. Also, Applicant's assert that Tara is in a non-analogous field. (4) Neither Bachtisi nor Tarara disclose microspheres wherein aldehydes on the microspheres are neutralized. (5) Applicant asserts that neither Bachtisi nor Tarara disclose microspheres comprising cross-linked polyvinyl alcohol. (6) Applicant asserts that the cited prior art documents do not disclose that the microspheres are useful for embolization, as does the instant invention. (7) Applicant asserts that the Examiner cites Tarara s teaching that the polyvinyl alcohol and acrylic acid polymers are equivalent microsphere structures but does not provide a citation to such alleged teaching.

While Bachtisi discloses polyvinyl alcohol cross linked microspheres and that the NaOH is used to remove unreacted chemicals, that does not mean that the NaOH does not neutralize the aldehydes on the microsphere since a compound is inseparable from its properties. For example, in the office action mailed 10/30/06, pages 4-5, bridging paragraph, it was noted that in Hawley's 12th Edition, 1993, Condensed Chemical Dictionary by Richard J. Lewis, Sr. pages 1058-1059, one of the possible uses of sodium hydroxide is as a neutralizing agent. In addition, **Figge et al** (US Patent No. 6,242,512) is made of record to illustrate that NaOH is a neutralizing agent that may be used with polyvinyl alcohols and support the Examiner's position that the addition of NaOH to the mixture of Bachtisi, for example, would behave as a neutralizing agent. In particular, Figge et al disclose redispersible polymer powders based on a mixture of a water insoluble, film forming polymer, and a water-soluble atomizing protective colloid

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(see entire document, especially, abstract; column 1, lines 8-13). Figge et al disclose that polyvinyl alcohols are chiefly employed as the protective colloids (column 1, lines 35-38). For the atomizing protective colloid component (i.e., polyvinyl alcohols), neutralization may be performed by redispersing a dispersion powder composition. The amount of neutralizing agent in the powder is selected such that the desired pH range is established on redispersion. An alternative possibility comprises redispersing or dispersing a dispersion powder composition or dry formulation which is not modified with neutralizing agent in water and establishing the desired pH range by subsequent addition of neutralizing agent. Possible neutralizing agents include NaOH. Thus, a skilled practitioner in the art would recognize that the combination of a polyvinyl alcohol with a neutralizing agent such as NaOH is not an uncommon combination. Hence, the skilled practitioner in the art would recognize that the aldehydes on the microsphere in the presence of NaOH would be neutralized like those in Applicant's invention.

While Applicant discloses the used of Tris-HCl in the specification, the claims are not limited to Tris-HCl as the neutralizing agent.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA

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1971). In particular, Tarara discloses the use of microsphere compositions that may comprise polyvinyl alcohol and contain various cell adhesion promoters (enzymes, peptides, polynucleotides, etc.) and anti-antigenic agents (steroids, peptides, proteins, etc.).

In response to applicant's argument that Tarara is nonanalogous art, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, the reference is directed to microstructures (i.e., microspheres) which may optionally comprise polyvinyl alcohol (see column 4, lines 37-46; columns 11-12, bridging paragraph, especially, column 12, line 2). Thus, a skilled practitioner would be motivated to utilize the teachings of Tarara which like Applicant's invention disclose polyvinyl alcohol compositions.

Furthermore, it is noted that the composition/product of the prior art is the same/similar as that being claimed by Applicant. Although, the cited prior art does not disclose the particular use, the composition/product would be capable of having the same use as Applicant's inventions since a composition/product and its properties are inseparable. Thus, Applicant's composition/product, like the cited prior art, would be 'capable of' performing the same function.

In the office action mailed 10/30/06, the Examiner respectfully requested Applicant to refer to a previous section wherein Tara et al was discussed in detail. On

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page 6 of the office action, lines 10-14, it is disclosed that Tarara et al disclose polyvinyl alcohols and acrylic acid copolymers and where support can be found for such teaching is disclosed.

In conclusion, based on the teachings of the prior art, inherent properties of compounds, and parameters that would be obvious to a skilled practitioner in the art, the cited prior art rejections are deemed proper.

4. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

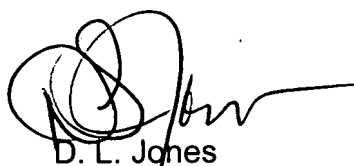
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (571) 272-0617. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m..

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

A handwritten signature in black ink, appearing to read 'D. L. Jones', with a stylized flourish extending to the right.

D. L. Jones
Primary Examiner
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July 9, 2007